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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/808,701   | 03/25/2004  | Philippe Msika       | 065691-0355         | 6071             |
| 22428  | 7590        | 12/23/2008           | EXAMINER            |                  |
| FOLEY AND LARDNER LLP<br>SUITE 500<br>3000 K STREET NW<br>WASHINGTON, DC 20007 |             |                      |                     | YU, GINA C       |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1611   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/808,701             | MSIKA, PHILIPPE     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | GINA C. YU             | 1611                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on August 6, 2008 and November 14, 2008.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/06/08, 11/14/08</u> .                                      | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2008 has been entered.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on November 14, 2008 and August 6, 2008 was filed after the mailing date of the Office action on July 6, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-6, 8-10, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport (US 5444091) in view of Frei et al (Internat'l J. of Cosmetic Science) (“Frei”).**

Rapaport teaches a method of treating striae distensae lesions (stretchmarks) by topically applying to the affected skin a composition comprising alpha-hydroxy acids in the amount ranging from 2-30 % by weight, more preferably 5-20 % by weight. See

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Example; instant claims 1 and 9. The reference teaches lactic acid. See col. 3, lines 36 – 45; instant claim 10. The reference teaches that the composition promotes rigidity and elasticity of the skin; the reference indicates that alpha hydroxy acids elicits a hyperplastic response in the epidermis and dermis that counters the breakdown of collagen cross linking and/or stimulates the production of materials which promote both rigidity and elasticity of the skin. See col. 4, lines 31 – 38.

While Rapaport teaches adding other ingredients including anti-oxidants and botanical extracts and to protect, prepare or mediate the action of the composition on the skin, the reference fails to teach soya protein.

Frei teaches fermented soya peptide extracted from Lactobacillus bacterium stimulate collagen formation and elastin synthesis when applied to skin, and increases skin firmness, elasticity, and tone. See abstract; instant claims 1-4. The peptide is said to have molecular weight of 800-1300 Daltons. See p. 161; instant claim 5-6.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the composition of Rapaport by incorporating soya peptide, as motivated by Frei, because Rapaport 1) teaches that stretchmarks are treated by countering the breakdown of collagen cross linking and/or stimulating production of materials which promotes the rigidity and elasticity of the skin, and 2) suggests adding additives to enhance the performance of the product; and Frei teaches that soya protein stimulates collagen formation and elastin synthesis, thereby improving firmness and elasticity of skin. The skilled artisan would have had a reasonable expectation of successfully improving the method of treating stretchmarks since soya is expected to

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improve the firmness and elasticity of the skin by stimulating collagen and elastic synthesis.

**Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport and Frei as applied to claims 1-6, 8-10, 21, and 22 as above, and further in view of Andary et al. (US 5719129) (“Andary”)**

The combined references fail to teach the amount by which soya peptide is used in a topical composition.

Andary discloses an anti-aging cream comprising 25 % of oraposide encapsulated in liposomes, which contains soya protein in 1 % by the total weight of the oraposide liposomes. See Example 8; instant claim 7.

It would have been obvious to a skilled artisan to modify the teaching of the combined references by adding soya peptide in the amount as suggested by Andary. The skilled artisan would have been motivated to incorporate the teaching of Andary to the Rapaport/Frei prior art because all references are directed to topically treating aged skin, and Andary teaches the specific amount by which soya peptide is used in an anti-aging formulation.

**Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport and Frei as applied to claims 1-6, 8-10, 21, and 22 as above, and further in view of Flick (Cosmetic and Toiletry Formulations, 1995)**

The combined references fail to teach the pH of the composition.

Flick teaches that an alpha hydroxy acid cream comprising 14.2 % of lactic acid (88%) is formulated to pH of 3.5. See p. 114.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to formulate the composition of the combined references to pH of 3.5 as motivated by Flick because Rapaport teaches an alpha hydroxy acid cream wherein the alpha hydroxy acid is lactic acid used up to 30 % by weight; and Flick teaches the suitable pH of 14.2 % lactic acid (88%) composition. The skilled artisan would have had a reasonable expectation of successfully producing a stable alpha hydroxy acid cream composition that is suitable for topical application.

**Claims 12-17, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport in view of Quelle (DE 4244418, English translation).**

Rapaport, as discussed above, teaches a method of treating stretchmarks by topically applying to the affected skin a composition comprising alpha-hydroxy acids in the amount ranging from 2-30 % by weight, more preferably 5-20 % by weight. See Example; instant claims 12, 15-17.

Rapaport fails to teach tripeptide consisting of the amino acids glycine, histidine, and lysine.

Quelle teaches the use of tripeptide Gly-His-Lys in cosmetic compositions to treat the skin against aging by increasing the radical scavenger effect and the stimulation of collagen synthesis of fibroblasts. See translation, p. 4, 16, Since the reference illustrates in Application Examples 3-5 the amount of a similar but “slightly different” tripeptide preparation Gly-His-Lys used for the same purposes, it would have been

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obvious to a skilled artisan to use tripeptide Gly-His-Lys in this amount. See instant claim 16. The reference also teaches preparation of peptide-trace element complexes by conjugating the tripeptides with copper(II) acetate monohydrate on page 16, and the mineral substances and trace elements that are suitable for this purpose include zinc.

See Claim 4, instant claims 13

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the composition of Rapaport by incorporating the tripeptide Gly-His-Lys, as motivated by Quelle, because Rapaport 1) teaches that stretchmarks are treated by countering the breakdown of collagen cross linking and/or stimulating permanent production of materials which promotes the rigidity and elasticity of the skin, and 2) suggests adding additives to enhance the performance of the product; and Quelle teaches that the tripeptide promotes collagen synthesis and better antioxidant activity. The skilled artisan would have had a reasonable expectation of successfully enhancing the method of treating stretchmarks, since it is expected that the tripeptide would treat aging symptoms of the skin. .

**Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport and Quelle as applied to claims 12-17, 23, and 24 as above, and further in view of Flick.**

The combined references fail to teach the pH of the composition.

Flick teaches that an alpha hydroxy acid cream comprising 14.2 % of lactic acid (88%) is formulated to pH of 3.5. See p. 114.

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It would have been obvious to one of ordinary skill in the art at the time of the present invention to formulate the composition of the combined references to pH of 3.5 as motivated by Flick because Rapaport teaches an alpha hydroxy acid cream wherein the alpha hydroxy acid is lactic acid used up to 30 % by weight; and Flick teaches the suitable pH of 14.2 % lactic acid (88%) composition. The skilled artisan would have had a reasonable expectation of successfully producing a stable alpha hydroxy acid cream composition that is suitable for topical application.

**Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport in view of Frei and Quelle.**

The references are discussed above. Rapaport teaches a method of topically applying alpha hydroxy acid cream to treat stretchmarks in skin.

The reference fails to teach soya peptide and tripeptide consisting of Gly-His-Lys.

Frei teaches fermented soya peptide extracted from Lactobacillus bacterium for increasing skin firmness, elasticity, and tone. See abstract; instant claims 1-4. The peptide is taught as have a molecular weight of 800-1300 Daltons. See p. 161; instant claim 5-6.

Quelle teaches the use of tripeptide Gly-His-Lys in cosmetic compositions to treat the skin against aging and as radical scavenger (antioxidant). See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the method of Rapaport by adding to the alpha hydroxy acid composition soya peptide and tripeptide, as motivated by Frei and Quelle, respectively. The motivation is found in the combined teachings of the references, as 1) Rapaport

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teaches that stretchmarks are treated by promoting the rigidity and elasticity of the skin, and suggests adding additives to enhance the performance of the product; such as botanical extracts and antioxidants; 2) Frei teaches that soya peptide effectively improves elasticity and firmness of the skin; and 3) Quelle teaches that the tripeptide promotes collagen synthesis and better antioxidant activity. The skilled artisan would have had a reasonable expectation of successfully enhancing the method treating stretchmarks since soya peptide and tripeptide are anti-aging agents suitable for cosmetic formulations.

***Oath/Declaration***

Declaration filed under 37 C.F.R. 1.132 on November 11, 2008 has been fully considered but does not place the present claims in allowable condition.

Declarant states that the one reading the Rappaport patent would not have concluded that stretchmarks are treated by promoted rigidity and elasticity of the skin. Declarant asserts that there is no test data supporting the statement in the reference alpha hydroxy acids, the main active ingredient of the Rappaport patent, stimulates glycosaminoglycans which promotes both the rigidity and elasticity of the skin. While declarant asserts that such data is speculative and unproven, examiner views that the disclosure of a patent should be considered objective teachings made available to one of ordinary skill in the art, as well as to applicant. Examiner is of opinion that whether a routineer would have doubted the publication is a subjective matter. Similarly, the declarant's opinion that a skilled artisan would not have found motivation to make the present invention in view of the Frei disclosure is also viewed subjective.

Declarant's opinion that Rapaport and Frei are nonanalogous arts is not viewed persuasive. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Rapaport and Frei are directed to treating dermal atrophy by enhancing the skin firmness, elasticity, and tone, by administering active ingredients which preserves collagen and/or promote collagen synthesis, as applicant has done in this case.

Declarant also states that etiologies of stretch marks and skin aging differ greatly, and most stretchmark treatment products do not contain antiaging components. However, literatures cite skin aging as one of the causes of stretch marks, and both conditions have been subject to treatments that enhance collagen synthesis or reduce collagen degradation. See US 5804594, US 4054649. Thus, examiner views that evidence of record weighs against the declarant's statements.

### ***Response to Arguments***

Applicant's arguments filed on August 6, 2008 and November 14, 2008 have been fully considered but they are moot in view of the new grounds of rejection in part, and not persuasive in part.

Applicant appears to argue that a *prima facie* case of obviousness requires that prior arts must provide the specific mechanism by which the claimed invention works. In this case, while applicant admits that Frei teaches "soya peptide . . . increases skin

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firmness, elasticity, and tone", applicant asserts that the reference lacks any objective measurement of skin firmness, elasticity, and tone. Applicant continues to argue that reference at best indicates the efficacy of the soya protein may or may not work.

Examiner views that the fact the reference does not indicate the specific mechanism of the soya peptide would not have been a deterrence to a skilled artisan to use soya peptide to obtain skin with improved firmness, elasticity, and tone; to one of ordinary skill in the art, the reference would have provided sufficient motivation to make the present invention.

Applicant also asserts that a skilled artisan would not have been motivated to combine Frei and Rapaport because the prior arts do not provide that soya peptide acts by eliciting a hyperplastic response as glycolic acid does. Examiner reiterates that a skilled artisan would have considered Frei's teaching that soya protein improves the firmness and elasticity of skin to use the active ingredient to make the present invention.

With respect to the rejection made in view of Rapaport and Quelle, applicant continues to argue that the rejection is improper, and asserts that the rejection is based on an identification of the Gly-His-Lys tripeptide. Examiner respectfully disagrees, because the rejection specifically cites the function of the tripeptide in treating aging skin as an antioxidant and by stimulating collagen synthesis of fibroblasts. The reference provides that a skilled artisan would have taken the tripeptide as a collagen synthesis stimulant which is known to be effective in treating stretchmarks. It is viewed that the routineer would have been motivated to combine the teachings of the references and make the present invention as applicant has done in this case.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/  
Primary Patent Examiner, Art Unit 1611